IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA, Plaintiff, v. Undetermined quantities of the articles of drugs listed below, in various sizes and types of containers, labeled and unlabeled, which are in the possession of Beehive Botanicals, Inc., 16297 West Nursery Road, Hayward, Wisconsin: <u>Finished Products</u>: Propolis Extract - Alcohol Free Propolis Tincture 50% Propolis Tincture 65% Propolis Capsules, 500 mg Propolis Tablets, 500 mg PropolPom Capsules, 500 mg Propol Dent Gum Propolis Derma Cream Propolis & Herb Throat Spray Propol-Guard Lip Balm Whole Grain Pollen Capsules, 500 mg Pollen Tablets, 500 mg Pollen Granules Royal Jelly Capsules, 500 and 1000 mg, pure Royal Jelly in Honey, 15,000 and 30,000 mg Fresh Royal Jelly Bee Therapy Foot Balm Bee Therapy Hand Salve Honey and Pollen Body Moisturizer Hydrating Cream Moisturizing Facial Cleanser Conditioning Shampoo Moisturizing Conditioner Honey and Cornmeal Bath Bar Honey Silk Night Cream <u>Bulk Components</u>: Propolis Extract (Propolis Bee Concentrate) Propolis, unprocessed or washed Royal Jelly Powder	Case No. 10-cv-158

Fresh Royal Jelly
Bee Pollen (Granules)
Honey,

and

all articles of drugs comprised, in part,
of these components,

Defendants.

CONSENT DECREE OF CONDEMNATION AND INJUNCTION

The United States of America ("United States"), by its attorney Stephen P. Sinnott, United States Attorney for the Western District of Wisconsin, by Leslie K. Herje, Assistant United States Attorney for that District, filed a Verified Complaint ("Complaint") for Forfeiture *In Rem* against the Defendant Articles ("Articles") on March 25, 2010.

Specifically, the Complaint alleges that the Articles proceeded against are drugs within the meaning of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 321(g)(1)(B), because their labeling, including information through links on Beehive Botanicals, Inc.'s websites, establish that they are intended to be used in the cure, mitigation, treatment, and prevention of disease in man. The Complaint also alleges that the Articles may not be introduced or delivered for introduction into interstate commerce pursuant to 21 U.S.C. § 355(a), because they are new drugs within the meaning of 21 U.S.C. § 321(p) and there are no approvals of applications filed with the Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(b) or exemptions from such requirements pursuant to 21 U.S.C. § 355(i) in effect for such drugs. The Complaint also alleges that the Articles are misbranded while held for sale after

shipment of one or more of their components in interstate commerce within the meaning of the Act, 21 U.S.C. § 352(f)(1), because their labeling fails to bear adequate directions for use, a requirement from which they are not exempt under 21 C.F.R. § 201.115 because they are unapproved new drugs. Furthermore, the Complaint alleges that, by reason of the foregoing, the Articles are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation pursuant to 21 U.S.C. § 334.

Pursuant to a Warrant of Arrest *in Rem* issued by this Court, the United States Marshal for the Western District of Wisconsin seized the Articles on March 31, 2010. On April 9, 2010, Beehive Botanicals, Inc. ("Beehive" or "Claimant"), through its attorneys, intervened and filed a claim to the seized Articles. Beehive is the sole claimant in this action.

WHEREAS Claimant having appeared and consented, without contest, to entry of this Decree under 21 U.S.C. § 334(d) condemning all of the Articles under seizure and forfeiting them to the United States, and the Court having been fully advised of the basis thereof, pursuant to the request of the parties hereto, it is now

ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over this action and the parties pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 334.

2. Claimant affirms that it is the sole owner of the seized Articles and that no other person has an interest in the Articles. Claimant further affirms that it will hold the United States harmless should any party or parties hereafter file or seek to file a claim to intervene in this action, or seek to defend or to obtain any part of the Articles subject to this Decree.

3. The seized Articles are drugs that are misbranded, as alleged in the Complaint.

4. The seized Articles, therefore, are condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

5. Within twenty (20) business days of entry of this Decree, Claimant shall, pursuant to 21 U.S.C. § 334(e), pay to the United States all court costs, service fees, storage costs, and other proper expenses of this proceeding incurred to date, and such further expenses, costs, and fees that may be incurred and taxed pursuant to 21 U.S.C. § 334(e).

6. Pursuant to 21 U.S.C. § 334(d)(1), within twenty (20) business days from the date of entry of this Decree, Claimant shall execute and file with the Clerk of this Court a good and sufficient penal bond in the form of an irrevocable stand by letter of credit ("Bond") in the amount of $200,000 in a form acceptable to the Clerk of this Court, to be applied to Lot 1 (as described in Paragraph 11(A) of this Decree) and held for application to succeeding Lots 2-6 (as described in Paragraphs 11(B)-(F) of this Decree), payable to the United States of America, and conditioned on Claimant's abiding by and performing all of the terms and conditions of this Decree and of such further orders and decrees as may be entered in this proceeding. Said irrevocable standby letter of credit shall be obtained from a trust company or commercial bank in good standing, shall be valid for at least ninety (90) days from the date this Decree is entered, and may be drawn upon by the presentation of a sight draft.

7. After paying the costs pursuant to Paragraph 5 and posting the Bond specified in Paragraph 6, Claimant shall give written notice to the Director, Minneapolis District Office, United States Food and Drug Administration ("FDA"), 250 Marquette

Avenue, Suite 600, Minneapolis, Minnesota 55401, that Claimant, at its own expense, is prepared to attempt to bring the condemned Articles into compliance with the law under the supervision of a duly authorized representative of the FDA ("FDA representative").

8. Claimant shall not commence attempting to bring the condemned Articles into compliance with the law until Claimant has submitted to the FDA representative a written statement detailing a proposed plan to achieve such compliance and has received from the FDA representative written authorization to commence implementing such plan. Such plan shall require, but not be limited to, ceasing the distribution, through all means, whether directly or indirectly, of claims that the Articles, or their bee-derived component ingredients, are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and which cause them to be drugs, pursuant to 21 U.S.C. § 321(g)(1)(B).

9. Until the condemned Articles have been released in writing by the FDA representative for shipment, sale, or other disposition, the United States Marshal for this District shall retain custody of the condemned Articles.

10. Claimant shall at no time, and under no circumstances whatsoever, ship, sell, offer for sale, or otherwise dispose of any part of the condemned Articles until (1) a FDA representative has had free access to the Articles in order to take any samples or make any tests or examinations that he or she deems necessary, and (2) a FDA representative has, in writing, released the Articles for shipment, sale, or other disposition.

11. The United States Marshal, upon receiving notice from the FDA in writing that Claimant is authorized to commence bringing the condemned Articles into

compliance with the law, shall release the appropriate Lot of condemned Articles (as described in Paragraphs 11(A)-(F)) from his custody to the custody of Claimant for the sole purpose of attempting to bring such articles into compliance with the law pursuant to the plan described in Paragraph 8. The schedule for release of the condemned Articles is as follows:

A. The Articles in Lot 1, consisting of approximately one-sixth (1/6) of the condemned Articles (by value), to be further designated by the FDA representative, for the sole purpose of attempting to bring Lot 1 into compliance with the law.

B. If and only if Claimant complies with all the terms of this Consent Decree with respect to Lot 1, and Lot 1 has been released, in its entirety, to Claimant in writing by FDA pursuant to Paragraph 9, the Articles in Lot 2, consisting of approximately one-sixth (1/6) of the condemned Articles (by value), to be further designated by the FDA representative, shall be released to Claimant for the sole purpose of attempting to bring Lot 2 into compliance with the law.

C. If and only if Claimant complies with all the terms of this Consent Decree with respect to Lot 2, and Lot 2 has been released, in its entirety, to Claimant in writing by FDA pursuant to Paragraph 9, the Articles in Lot 3, consisting of approximately one-sixth (1/6) of the condemned Articles (by value), to be further designated by the FDA representative, shall be released to Claimant for the sole purpose of attempting to bring Lot 3 into compliance with the law.

D. If and only if Claimant complies with all the terms of this Consent Decree with respect to Lot 3, and Lot 3 has been released, in its entirety, to Claimant in writing by FDA pursuant to Paragraph 9, the Articles in Lot 4, consisting of approximately one-sixth (1/6) of the condemned Articles (by value), to be further designated by the FDA

representative, shall be released to Claimant for the sole purpose of attempting to bring Lot 4 into compliance with the law.

E. If and only if Claimant complies with all the terms of this Consent Decree with respect to Lot 4, and Lot 4 has been released, in its entirety, to Claimant in writing by FDA pursuant to Paragraph 9, the Articles in Lot 5, consisting of approximately one-sixth (1/6) of the condemned Articles (by value), to be further designated by the FDA representative, shall be released to Claimant for the sole purpose of attempting to bring Lot 5 into compliance with the law.

F. If and only if Claimant complies with all the terms of this Consent Decree with respect to Lot 5, and Lot 5 has been released, in its entirety, to Claimant in writing by FDA pursuant to Paragraph 9, the Articles in Lot 6, consisting of approximately one-sixth (1/6) of the condemned Articles (by value), to be further designated by the FDA representative, shall be released to Claimant for the sole purpose of attempting to bring Lot 6 into compliance with the law.

12. If the FDA representative has provided a written release of the condemned Articles for shipment, sale, or other disposition, Claimant's subsequent shipment, sale, or other disposal of the Articles or any part of them shall not be performed in a manner contrary to the provisions of the Act or of the laws of any State or Territory (as defined in the Act) in which the Articles are disposed of or sold.

13. If requested by the FDA representative, Claimant shall furnish duplicate copies of invoices of sale of the released Articles, or such other evidence of disposition as the FDA representative may request.

14. Within sixty (60) business days of the entry of this Decree, Claimant shall, under the supervision of the FDA representative, either complete the process of

attempting to bring the condemned Articles into compliance with the law or destroy the condemned Articles. The FDA representative's decision regarding the adequacy of Claimant's attempt to bring the Articles into compliance with the law shall be final.

15. The United States Attorney, upon being advised by a FDA representative that the condemned Articles have been brought into compliance with the Act and the requirements of this Decree, or destroyed in compliance with this Decree, and that Claimant has paid all costs submitted to Claimant as of that date, will transmit such information to the Clerk of this Court, whereupon the Bond given in this proceeding shall be returned to the Claimant.

16. If Claimant has not completed the process of destroying or attempting to bring the condemned Articles into compliance with the law, as set forth in Paragraph 14, prior to the expiration of the original Bond, or any subsequent Bond, it shall be the Claimant's responsibility to execute and file with the Clerk of this Court a new Bond, valid for at least an additional ninety (90) days, no later than thirty (30) days before the expiration of the previous Bond, and to provide written notice of the posting of such new Bond and a copy thereof to both FDA at the address specified in Paragraph 27 and the United States Attorney's Office. If, thirty (30) days before the expiration of the original Bond or any subsequent bond, Claimant has not completed the process of destroying or attempting to bring the condemned Articles into compliance with the law and has not filed a new Bond with the Clerk of this Court, the existing Bond shall be immediately payable to the United States of America prior to expiration of such Bond.

17. If Claimant does not avail itself of the opportunity to bring the condemned Articles into compliance or destroy them in the manner stated, the United States Marshal shall retain custody of the condemned Articles, pending an order by this

Court regarding their disposition. In the event that it becomes necessary for the United States Marshal to retain custody of the Articles pursuant to this Paragraph, Claimant shall be responsible for all costs of storage and disposition that are incurred by the United States.

18. If Claimant breaches any conditions stated in this Decree, or in any subsequent decree or order issued in this proceeding, prior to successfully bringing the condemned Articles into compliance with the law or disposing of the condemned Articles as set forth in paragraph 12, Claimant shall, at its own expense, immediately return the condemned Articles to the United States Marshal or otherwise dispose of them pursuant to an order of this Court. In the event that return of the Articles becomes necessary pursuant to this Paragraph, Claimant shall be responsible for all costs of storage and disposition that are incurred by the United States.

19. Should Claimant fail to abide by and perform all of the terms and conditions of this Decree or of the Bond posted in this proceeding, then the Bond shall, on motion of the United States in this proceeding, be forfeited in its entirety to the United States of America and judgment entered thereon, and any condemned Articles remaining in the custody of the United States Marshal shall be forfeited and disposed of pursuant to further Order of this Court.

20. Immediately upon entry of this Decree, Claimant and each and all of its directors, officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, are prohibited from directly or indirectly doing or causing any of the following acts:

A. Introducing or delivering for introduction into interstate commerce, or manufacturing, processing, packing, promoting, labeling, or advertising any new drug

that Claimant claims or represents, directly or indirectly, as being safe and effective for the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, unless and until (a) an approval of an application filed with FDA pursuant to 21 U.S.C. § 355(b) authorizing each and every such claim or representation is in effect for each such product, or (b) an acceptable notice of claimed investigational exemption filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R Part 312, is on file for each such product;

B. Introducing or delivering for introduction into interstate commerce any misbranded drug, within the meaning of 21 U.S.C. § 352; and

C. Misbranding any drug, within the meaning of 21 U.S.C. § 352, while such drug is held for sale after shipment of one or more components in interstate commerce.

21. If Claimant fails to comply with the provisions of this Decree, Claimant shall pay to the United States of America liquidated damages in the sum of one thousand dollars ($1,000.00) for each day the Consent Decree is violated and one thousand dollars ($1,000.00) for each shipment (of any amount) of unapproved new drug. Claimant understands and agrees that the liquidated damages specified in this Paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, criminal or civil penalties based on conduct that may also be the basis for the payment of the liquidated damages.

22. Claimant shall reimburse the United States for costs associated with any inspections (including supervision of destruction), examinations, evaluations, record reviews, or analyses conducted pursuant to this Decree, at the standard rates prevailing at the time the activities are accomplished. As of the date of entry of this Decree, these rates are: $87.57 per hour and fraction thereof per representative for inspection and

supervision work other than laboratory and analytical work; $104.96 per hour and fraction thereof per person for laboratory and analytical work; $0.50 per mile for travel by automobile; the government rate or equivalent for travel by air; and the published government per diem rate, or the equivalent, for the areas in which the inspections are performed, per representative for subsistence expenses, where necessary. In the event that the standard rates generally applicable to the FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

23. Within fourteen (14) business days of entry of this Decree, Claimant shall retain an independent person or persons (the "Expert"), without personal, financial (other than the consulting agreement between the parties), or familial ties to Claimant or its owners or employees, who by reason of background, experience, education, and training is qualified to assess Claimants' compliance with the Act, to review the claims Claimant makes for each of their products on their product labels, labeling, promotional material, and any websites owned or controlled by Claimant including, but not limited to websites referenced, linked to, endorsed, or adopted directly or indirectly by Claimant ("Expert Review").

A. At the conclusion of the Expert Review, the Expert shall prepare a written report analyzing whether Claimant is operating in compliance with the Act, and in particular, certify whether Claimant continues to have any claims on its product labels, labeling, promotional materials, websites owned or controlled by Claimant, or in any other media, including, but not limited to websites referenced, linked to, endorsed, or adopted directly or indirectly by Claimant, that cause any of its products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g). The Expert shall submit this report concurrently to FDA and Claimant within twenty (20) business days of the entry of this Decree.

B. If the Expert reports any violations of the Act, Claimant shall, within seven (7) business days of receipt of the report, correct all of the violations. If Claimant believes it is unable to correct all of the violations within seven (7) business days, Claimant shall submit a written notification to FDA explaining why the corrective actions cannot be completed within that time frame and shall provide a proposed schedule for completion of the corrective actions that does not exceed twenty (20) business days. Claimant shall correct the violations in accordance with its proposed schedule, unless FDA notifies Claimant that a shorter time frame is required.

C. An Expert Review shall be conducted annually for no less than three years after the completion of the initial Review described in this Paragraph. Claimant may use the same Expert for each Expert Review conducted.

D. For each annual Expert Review, the Expert shall submit his or her report concurrently to FDA and Claimant within twenty (20) business days from the completion of the Review. If the Expert reports any violations of the Act, Claimant shall, within seven (7) business days of receipt of the report, correct all of the violations. If Claimant believes they are unable to correct all of the violations within seven (7) business days, Claimant shall submit a written notification to FDA explaining why the corrective actions cannot be completed within that time frame and shall provide a proposed schedule for completion of the corrective actions that does not exceed twenty (20) business days. Claimant shall correct the violations in accordance with its proposed schedule, unless FDA notifies Claimant that a shorter time frame is required.

E. If the Expert does not report any violations of the Act for three consecutive annual Expert Reviews, Claimant may request in writing, at the address specified in Paragraph 27, to discontinue the periodic Expert Reviews.

24. Claimant and each and all of its directors, officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or

participation with any of them, shall cease and discontinue all promotion, marketing, and distribution of any article of drug, as defined by 21 U.S.C. § 321(g), upon written notice from the Director, FDA Minneapolis District Office, that such article is a drug that (1) is misbranded within the meaning of 21 U.S.C. § 352(f)(1), because its labeling fails to bear adequate directions for use, or (2) is a new drug that is not the subject of an approved new drug application. As part of such notification, FDA may order that Claimant recall misbranded and unapproved new drugs already distributed. Any cessation of operations pursuant to this Paragraph that results from violations relating to products listed in the Complaint shall be initiated by Claimant immediately upon receipt of written notice from the Director. Any other cessation of operations pursuant to this Paragraph shall be initiated by Claimant within ten (10) business days of receipt of written notice, unless Claimant seeks review of the notice by this Court, in which case the notice will be stayed until resolution of the dispute by this Court. Any recall ordered by FDA shall be initiated by Claimant within ten (10) business days of receipt of the order unless Claimant seeks review of the order by this Court, in which case the order will be stayed until resolution of the dispute by this Court.

25. Any cessation of operations as described in Paragraph 24 of this Decree shall continue until Claimant receives written notice from FDA that Claimant appears to be in compliance with the requirements of the Act.

26. Duly authorized representatives of FDA shall be permitted, as and when FDA deems necessary and without prior notice to Claimant, to make inspections of Claimant's facilities or of any new location(s) at which Claimant operates, including buildings, equipment, finished and unfinished materials, containers, and labeling; to take photographs and make videotape recordings; to collect samples of any finished or unfinished materials and products, containers, and labeling; and to examine and obtain copies of all records in Claimant's possession or control relating to the promotion,

marketing, manufacturing, and distribution of any and all products, and, without prior notice, to take any other measures necessary to monitor and ensure continuous compliance with the terms of this Decree. The costs of all such inspections and sample analyses shall be borne by Claimant at the rates specified in Paragraph 22 of this Decree. Such inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority of this Decree is apart from, and in addition to, the authority to make inspections set forth in 21 U.S.C. § 374.

27. All notifications, correspondence, and communications to FDA required by this Decree shall be addressed to the Director, Minneapolis District Office, United States Food and Drug Administration, 250 Marquette Avenue, Suite 600, Minneapolis, Minnesota, 55401, and shall reference the civil action number.

28. Claimant shall bear its own costs and attorneys' fees in connection with this action.

29. Should the United States bring, and prevail in, a civil or criminal contempt action arising out of the violation of any term of this Decree, Claimant shall pay attorneys' fees and all expenses, including travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and analytical and investigational expenses, incurred by the United States in bringing such an action.

30. Defendants shall abide by the decisions of FDA, which decisions shall be final. FDA decisions under this Decree shall be reviewed by the Court, if contested, under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be authorized or allowed by either party.

31. No sooner than sixty (60) months after entry of this Decree, Claimant may petition this Court for an order to dissolve the Decree. If claimant has maintained, to FDA's satisfaction, a state of continuous compliance with this Decree, the Act, and all

applicable regulations during the sixty (60) months preceding Claimant's petition, the Government will not oppose such petition.

32. This Court retains jurisdiction over this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED:

Entered this 14th day of May, 2010

Barbara B. Crabb
U.S. District Court Judge